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EXAMINER

BAXTER, JESSICA R

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 08/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/746,746

Applicant(s)

AINSWORTH ET AL. *Ch*

Examiner

Jessica R Baxter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 April 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 22-35 is/are rejected.
- 7) ☒ Claim(s) 21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Information Disclosure Statement*

1. The information disclosure statement filed April 12, 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. No copies were provided.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 11, 14, 15, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,925,061 to Ogi et al. Ogi discloses a stent comprising a plurality of cylindrical rings (see FIG. 1 members 15) and at least one flexible link attaching each cylindrical ring to an adjacent cylindrical ring (see FIG. 1 bridges 18), the link including a bounded aperture having at least one aperture defining portion disposed generally transverse to the stent longitudinal axis (see FIG. 5b bridge 38b).

Regarding claim 2, Ogi discloses the bounded aperture comprises two aperture defining portions generally perpendicular to stent longitudinal axis (see FIG. 5b).

Regarding claim 11, Ogi discloses that each cylindrical ring comprises peaks and valleys in phase with the peaks and valleys of an adjacent cylindrical ring (see FIG. 1).

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Regarding claims 14, 15, and 16, Ogi discloses that stainless steel, a shape memory alloy, or a pseudo-elastic metal alloy may be used to form the stent (see Column 6 lines 14-19).

*Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 2, 7, 8, 9, 10, 11, 14, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/32543 to Penn et al in view of Ogi et al. '061. Penn discloses a stent comprising a plurality of cylindrical rings (see FIG. 1) interconnected to form a stent, at least one flexible link (see FIG. 8 sidewalls 734 and 740) attaching each cylindrical ring to an adjacent cylindrical ring, and an undulating link (see FIG. 8 strut 770) within the wall of the ring (see Page 15 line 29- Page 16 line 7). Penn does not disclose a bounded aperture disposed in the link between the cylindrical rings. Ogi teaches that an aperture provides more compressibility in the direction aligned with the longitudinal axis of the stent and increases the bendability in radial directions (see Column 7 lines 52-67). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include an aperture in the flexible link of Penn's invention in order to increase flexibility and bendability of Penn's invention.

6. Claims 3, 4, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogi et al. '061. Ogi discloses the invention as claimed except for the shape of the bounded aperture. It would have been an obvious matter of design choice to change the shape of the bounded aperture of Ogi,

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since it has been held to be within the general skill of a worker in the art to select a known shape on the basis of its suitability for the intended use as a matter of obvious design choice.

7. Claims 12, 13, 17, 18, 20, 22, 23, 24, 25, 27, 29, 30, 31, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/32543 to Penn et al. in view of Ogi et al. '061 as applied to claims 1, 2, 7, 8, 9, 10, 11, 14, 15 and 16 above, and further in view of U.S. Patent No. 6,013,091 to Ley et al. Penn, as modified, discloses the claimed invention except for the tapered link portion connecting the link to the aperture portion. Ley discloses the use of a taper in order to limit recoil and add resistance to compression for an expanded stent while maintaining longitudinal flexibility and expandability (see Column 1 lines 25-35). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the link portion of modified Penn to include a tapered portion in order to limit recoil and add resistance to compression while maintaining longitudinal flexibility and expandability.

Regarding claims 20, 22, 23, and 29 Penn discloses an undulating link portion with a plurality of substantially straight portions disposed generally perpendicular to the stent longitudinal axis with a plurality of bends (see FIG. 8 strut 770).

Regarding claim 24, Penn discloses that each cylindrical ring comprises peaks and each ring's peaks are in phase with the peaks of the adjacent cylindrical ring (see FIG. 8).

Regarding claims 25 and 31, Penn discloses that the stent is formed from a tube (see Page 20 lines 4-14).

Regarding claims 27, 34 and 35, Penn, as modified, discloses a stent comprising a plurality of cylindrical rings having a plurality of U-shaped portions (see FIG. 9 wall 860), Y-shaped portions and (see FIG. 9 wall 860 and portion 836) W-shaped portions (see FIG. 9 wall 850).

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8. Claims 19 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/32543 to Penn et al. in view of Ogi et al. '061 and Ley et al. as applied to claims 1, 2, 7, 8-18, 20, 22-25, 27, 29-31, 34, and 35 above. Penn as modified, discloses the claimed invention except for the shape of the bounded aperture. It would have been an obvious matter of design choice to change the shape of the bounded aperture of modified Penn, since it has been held to be within the general skill of a worker in the art to select a known shape on the basis of its suitability for the intended use as a matter of obvious design choice.

9. Claims 26, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over over WO 97/32543 to Penn et al. in view of Ogi et al. '061 and Ley et al. as applied to claims 1, 2, 7, 8-18, 20, 22-25, 27, 29-31, 34, and 35 above, and further in view of EP 0806190 to Rolando et al. Penn, as modified, discloses the claimed invention except for the varying cross sections of the plurality of struts that form the cylindrical rings. Rolando discloses varying the cross sections in order to achieve optimal characteristics of plastic deformability and resistance to stress which may close the stent (see Column 11 line 31- Column 12 line 20). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cross sections of the plurality of struts of the modified invention of Penn in order to optimize the characteristics of plastic deformability and resistance to stress.

*Allowable Subject Matter*

10. Claim 21 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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*Conclusion*

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following patents are cited to further show the state of the art with respect to similar stents:

U.S. Patent No. 5,591,197 to Orth et al.

U.S. Patent No. 5,697,971 to Fischell et al.

U.S. Patent No. 5,843,175 to Frantzen

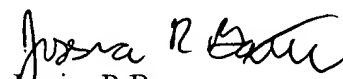
U.S. Patent No. 6,033,433 to Ehr et al.

U.S. Patent No. 6,200,337 to Moriuchi et al. U.S. Patent No. 6,325,821 to Gaschino et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

  
Jessica R Baxter  
Examiner  
Art Unit 3731

jrb  
August 12, 2002

  
MICHAEL J. MILANO  
SUPERVISORY PATENT EXAMINER  
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